

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/31/2007 has been entered.

### ***Response to Arguments***

2. Applicant's arguments have been considered but are not persuasive.

3. The applicant suggests that the prior art of Ray (US 4,800,903) teaches away from using fibrous polyethylene by indicating the use of "crystalline" and "amorphous" polyethylene and distinguishing these from "high density polyethylene". Below is the text of Ray:

The first polymeric substance is typically a material generically described as an olefinic polymer. More specifically, the first polymeric substance is preferably polyethylene or polypropylene but may also be any polyolefin or polyolefindiene such as polybutadiene, poly-1-butene, polyisobutylene, polyisoprene, poly-4-methyl pentene, or combinations thereof, for example. Of particular preference is formulating the porous plug 18 of the present invention is a high density polyethylene. Although amorphous rather than crystalline polyethylene appears to have a greater nicotine-absorptive capacity, porous plugs are more readily produced from high density polyethylene which has adequate capacity for reversible nicotine absorption. The porous plug may be produced mechanically and may also be a mass of filaments. (col. 5, 43-49, emphasis added).

It is clear for the disclosure of Ray that high density polyethylene is used because of the ease of manufacture ("more readily produced"), but does not indicate that either crystalline or amorphous polyethylene cannot be used. In fact, Ray appears to be indicating that although amorphous polyethylene is a better material for the intended purpose, it is not the most preferred due to difficulty in its use in commercial manufacturing.

4. The remaining arguments pertain to amended claim limitations rejected below.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3-5, 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. Claim 1 has been amended to claim a shaped mass comprising "non-fibrous polyethylene". This embodiment is not in the original claims and is not disclosed in the specification.

8. Claim 1 has been amended to claim a shaped mass comprising a mixture of "sintered fibrous and/or filamentous polyethylene". The original claims and specification

do not disclose the use of sintered fibrous and/or filamentous polyethylene in the shaped plug. Original claim 8 indicates that "said container further comprises sintered material" but does not indicate the use of the "sintered material" in the shaped mass or the use of polyethylene as the sintered material.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 15 recites the limitation "said polymeric material" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 15 originally depended from claim 11, which provided antecedent basis "wherein said fibers or filaments comprise polymeric material." Claim 15 no longer depends from claim 11, and therefore lacks proper antecedent basis and is unclear as to what material claim 15 is further defining.

### ***Claim Rejections - 35 USC § 103***

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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11. Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray et al. (4,800,903) in view of Perfetti et al. (4,924,883) and the applicant's admitted prior art.

12. Ray et al. disclose a preferred embodiment of a shaped mass of polyethylene filaments that releasably absorbs nicotine (col. 5, line 52-60) that is encapsulated in a nicotine-impermeable polymer film (i.e. non-fibrous) (col. 13, table 12). However, Ray et al. do not disclose whether the filaments are sintered, the presence of non-fibrous polyethylene, or the flow resistance of the container.

13. Although Ray et al. does not expressly state that the preferred embodiment of high density polyethylene is in the form of sintered fibers, the applicant admits that the prior art, including the disclosure of Ray et al., employ sintered fibers. The applicant states in paragraph 0021, that, "The above mentioned porous plugs [including Ray et al.] are manufactured through a sintering process." It would have been obvious to one of ordinary skill in the art at the time of invention that sintering would have been a well known technique to form porous plugs such as those used by Ray et al. as it is stated by the applicant in the discussion of prior art.

14. Ray et al. do not expressly teach the use of non-fibrous polyethylene in the shaped mass (porous plug). However, Ray et al. state that the porous plug may be made of polyethylene and that, "The porous plug may be produced mechanically and may also be a mass of filaments (col. 5, 47-49). The examiner interprets this to mean that although the porous plug may be made of filaments Ray et al. anticipates that there are other, non-filament, structures possible. Ray et al. also disclose several examples

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using non-filament polyethylene (polyethylene tubes—examples 1-3, 6, and 7; film—example 4) as well as some examples of fibrous materials. In addition, the examples disclose the use of Porex Porous Polyethylene Plug, but do not indicate whether the plug is foam or fibrous. It would have been obvious to one of ordinary skill in the art to use any form of polymeric material disclosed by Ray et al., or a combination of materials disclosed by Ray et al. The motivation to use various materials is indicated in the examples of Ray et al. that show different abilities of different structures and compounds to retain and release nicotine.

15. Flow resistance of cigarettes is well known. For instance, Perfetti et al. indicate that, “Typical pressure drop values for smoking articles range from 70 mm to 170 mm, preferably from about 90 mm to about 130 mm of water pressure drop at 17.5 ml/sec of air flow rate,” (col. 4, 15-19). The instant claims 1, 3 and 4 require between 30 mm to 101 mm of flow resistance at 16.6 ml/sec of air flow.

16. It would have been obvious to one of ordinary skill in the art at the time of invention to make a nicotine delivery container have a similar pressure drop to that of conventional cigarettes to make using such a nicotine delivery container similar to the use of conventional cigarettes. In addition, as admitted by the applicant, it would have been well know in the art how to alter the flow rate of the nicotine container without undue experimentation (page 6 of response, 2<sup>nd</sup> paragraph).

17. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ray et al. (4,800,903), Perfetti et al. (4,924,883), and the applicant’s admitted prior art as

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applied to claim 1 above, in further view of the applicants prior art. Ray et al. and Perfetti et al. do not disclose production of fibers or filaments by spinning and or extrusion. However, Ray et al., indicate that the plug containing nicotine, "may be produced mechanically and may also be a mass of filaments," (Col 5, line 52-60). The applicant has admitted that making fibers or filaments is known in the prior art by saying, "The fiber or filaments may be manufactured in a number of different ways known in the art, such as through extrusion and spinning," (paragraph 0039). It would have been obvious to one of ordinary skill in the art at the time of invention to use spinning and/or extrusion to make the fibers or filaments used in the invention.

18. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ray et al. (4,800,903), Perfetti et al. (4,924,883), and the applicant's admitted prior art as applied to claim 1 above, in further view of Rivers, Jr. (2,818,868). Although Ray et al. disclose using polyethylene terephthalate (PET) film for enclosing the fiber with absorbed nicotine, using PET as a fiber or filament is not disclosed. However, Rivers, Jr. discloses that PET can be used as a fiber in cigarette filters. In this similar application nicotine is retained and released by the filter made from PET during combustion of the tobacco. It would have been obvious to one of ordinary skill in the art at the time of invention to use PET and other fibers that have been shown capable of releaseably retaining nicotine in the present invention.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. FELTON whose telephone number is (571)272-4805. The examiner can normally be reached on Monday to Friday, 7:30 AM to 4:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Phillip C. Tucker can be reached on 571-272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJF

/Philip C Tucker/

Supervisory Patent Examiner, Art Unit 1791